

EXHIBIT 2

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Co-Lead/Liaison Counsel for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

**IN RE: BARD IVC FILTERS
PRODUCTS LIABILITY LITIGATION**

MD No. 02641

**PLAINTIFFS' SECOND SET OF
REQUESTS FOR PRODUCTION OF
DOCUMENTS**

Plaintiffs, by and through undersigned counsel and pursuant to Fed. R. Civ. P. 34, hereby request that Defendants CR Bard Incorporated and Bard Peripheral Vascular Incorporated produce the documents identified in the following Requests for Production of Documents within thirty (30) days of this Request. Production shall be made at the offices of Gallagher & Kennedy, P.A., 2575 East Camelback Road, Phoenix, Arizona 85016.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

1. The response to each Request shall include all documents within your possession, custody, or control, including, but not limited to, documents in the possession, custody, or control of your investigators, consultants, attorneys, or other agents. Any reference to "you" shall include your consultants, attorneys, or other agents.

2. As used herein, the term "document" means all written, recorded, and graphic and electronically stored matter of every type and description encompassed by

1 Fed. R. Civ. P. 34(a)(1), including, but not limited to, writings, graphs, charts,
2 photographs, sound recordings, images, drawings, notes, contracts, agreements,
3 correspondence, letters, memoranda, appointment books, calendars, all forms of
4 communication (including physical documents, e-mail, instant messaging, texts, tweets,
5 social-media postings and communications), and all electronically stored information in
6 any medium from which information can be obtained either directly or, if necessary, after
7 translation by the responding party into a reasonably usable form.

8 3. You shall produce any and all documents responsive to each Request unless
9 an objection is stated to a Request. If you object to all or any part of a Request, you shall
10 state the reasons for the objection. If objection is made to part of an item or category, the
11 part shall be specified. If you object to only part of an item or category, you shall produce
12 any and all documents responsive to the part or parts of the item or category to which you
13 do not object.

14 4. If you contend that an identified document would be excludable from
15 production, state the reasons for such objection or grounds for exclusion and identify each
16 person having knowledge of the factual basis, if any, on which the privilege or other
17 ground is asserted.

18 5. You should produce documents for inspection as they are kept in the usual
19 course of business or, alternatively, organize and label them to correspond with the
20 categories in the request.

21 6. Production of Electronically Stored Information (ESI).

22 a. Production of Native Form. ESI should be produced in native form
23 with all metadata intact unless such form would not be reasonably
24 usable by third parties (such as ESI from legacy or proprietary
25 systems).

26 b. Production in Non-Native Form for ESI not Reasonably Usable. If
27 ESI would not be reasonably usable by third parties, it should be
28 produced as follows:

1 Conversion to TIFF. ESI should be converted into *.tif image
2 format with single-page files at 300 DPI, Group IV compression,
3 with original orientation maintained. All available fielded metadata
4 and text-searchable information shall be extracted from the native
5 document and produced with the ESI as part of the document. Any
6 bates labeling on the *.tif images should be done in a consistent font
7 and should not obscure any visible text, image, or portion of the
8 original file.

9 Extracted Full Text. The producing party should produce the
10 full extracted text in the form of a single *.txt file for each non-native
11 file. The text file name shall correspond to the bates label of the
12 associated document.

13 Production of Metadata. The producing party should provide
14 the following metadata (as applicable by file type) for all ESI:
15 begdoc, enddoc, begattach, endattach, custodians, recordtype,
16 doctype, emailsubject, docauthor, to, cc, bcc, docdate, parentdate,
17 datesent, timesent, datercvd, timercvd, datelastmod, timelastmod,
18 datelastprint, timelastprint, filename, title, attachname, docext,
19 filesize, md5hash, numattach, pgcount, nativefile, textfile,
20 organization, comments, lastauthor, revision, and locations.

21 Production of Load File. For all Non-native productions, the
22 producing party should produce an appropriate data load file in
23 Concordance (.dat) format (DAT files should be produced in UTF8)
24 and image load file in Opticon (.opt) format.

25 Preservation of Document Relationships. In the production of
26 TIFF format images, the producing party should preserve all
27 relationships, such as parent-child, between documents by producing
28 relating documents sequentially. For parent documents with

1 attachments (or exhibits), the attachments should be produced as
2 independent files immediately following the main/parent document.
3 Likewise, embedded files should be produced as separate files as
4 attachments to the file in which they were embedded.

- 5 c. ESI with Links to other ESI or Database(s). For any ESI files that
6 contain links to other documents, files, ESI, web addresses, or to
7 database information, the producing party should ensure that the
8 relationship between the files is preserved and that such links remain
9 active. Where the form of production precludes the ability to have
10 active links, the producing party should produce copies of the linked
11 documents, files, ESI, or web addresses as related documents. If
12 produced ESI includes a link to a database or information in a
13 database, the producing party should provide reasonable access to the
14 database or to the database information in such a way that Plaintiffs
15 can reasonably access or determine the linked information.
- 16 d. ESI requiring Proprietary Software. If proprietary software
17 unavailable to Plaintiffs is required to review the producing party's
18 ESI in native form, the producing party should provide reasonable
19 access to the proprietary software for purposes of review of ESI by
20 Plaintiffs or their representatives.

21 7. For each document requested which you are unable to produce and which
22 was at any time in your possession, custody or control or which you had access to, specify
23 in detail:

- 24 a. The nature and author of the document;
25 b. All recipients of the document and any copies thereof;
26 c. A summary of the information contained in the document;
27 d. The date and manner in which you lost possession, custody or control
28 of the document;

- e. Identify all persons who had access to the document while it was within your possession, custody or control; and,
- f. Identify all persons who have knowledge of the contents of the document.

DEFINITIONS

1. "Bard" means C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.
2. "BPV" means Bard Peripheral Vascular, Inc.
3. "C.R. Bard" means C.R. Bard, Inc.
4. "FDA" means the federal Food and Drug Administration.
5. "IVC" means inferior vena cava.

REQUEST FOR PRODUCTION

Request for Production No. 9:

Complete complaint files from 1998 to the present for all Bard IVC filter products, including all information related to any IVC filter complaints or adverse events on Bard's Trackwise systems as well as the format of such files that predate the adoption of Trackwise.

Request for Production No. 10:

All internal policies and procedures in place at any time from 2003 to the present relating to:

- a. quality assurance,
- b. corrective or preventative actions,
- c. design controls,
- d. design testing,
- e. field assurance,
- f. post-market surveillance,
- g. complaint evaluation, investigation, or handling,
- h. risk management,

- i. risk evaluation,
- j. process for making a determine of malfunction versus serious injury,
- k. acceptance of incoming product, and
- l. inspection, testing, or other verification of incoming products as conforming to specified requirements.

This request includes all current and former policies and procedures relating to the foregoing subjects.

Request for Production No. 11:

All training materials that have been used at any time from 2003 to the present for quality assurance or complaint handling, including but not limited to materials in the form of procedures, standard operating procedures, forms, work instructions, training logs, training requirements, and testing or quizzes

Request for Production No. 12:

All documents that evince, relate, or refer to communications with King & Spalding regarding Bard's response to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, including but not limited to any and all drafts of communications to the FDA, emails or other communications relating to such drafts, as well as final communications in any form to the FDA.

Request for Production No. 13:

All documents that evince, relate, or refer to communications with Hogan Lovells regarding Bard's response to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance

1 of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and
2 January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, including
3 but not limited to any and all drafts of communications to the FDA, emails or other
4 communications relating to such drafts, as well as final communications in any form to
5 the FDA.

6
7 **Request for Production No. 14:**

8 All documents that evince, relate, or refer to any communications by King &
9 Spalding on behalf of Bard with the FDA regarding Bard's response to the FDA's
10 inspections of Bard facilities in October 2014 through January 2015 and the FDA's
11 findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and
12 BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning
13 Letter" to C.R. Bard, dated July 13, 2015.

14
15 **Request for Production No. 15:**

16 All documents that evince, relate, or refer to any communications by Hogan
17 Lovells on behalf of Bard with the FDA regarding Bard's response to the FDA's
18 inspections of Bard facilities in October 2014 through January 2015 and the FDA's
19 findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and
20 BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning
21 Letter" to C.R. Bard, dated July 13, 2015.

22
23 **Request for Production No. 16:**

24 All documents, files, or drafts that relate to the monthly reports provided to the
25 FDA by Bard in 2015 relating to the FDA's inspections of Bard facilities in October 2014
26 through January 2015 and the FDA's findings of violations, including the FDA's issuance
27 of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and
28 January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, including

1 but not limited to the native files of the “periodic updates” to the FDA on which Chad
2 Modra worked with King & Spalding or Hogan Lovells.

3
4 **Request for Production No. 17:**

5 The documents that reflect the personnel at King & Spalding in addition to Mr.
6 Niedelmann who worked with Chad Modra in responding to the FDA arising out of the
7 FDA’s inspections of Bard facilities in October 2014 through January 2015 and the
8 FDA’s findings of violations, including the FDA’s issuance of Form FDA-483s to C.R.
9 Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the
10 “Warning Letter” to C.R. Bard, dated July 13, 2015.

11
12 **Request for Production No. 18:**

13 All files for or communications with Dr. Shane Gad and/or Dr. Scott Terratola,
14 relating to the FDA’s inspections of Bard facilities in October 2014 through January 2015
15 and the FDA’s findings of violations, including the FDA’s issuance of Form FDA-483s to
16 C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the
17 “Warning Letter” to C.R. Bard, dated July 13, 2015, or Bard’s responses thereto.

18
19 **Request for Production No. 19:**

20 All communications with Dr. Shane Gad regarding IVC filter issues, including but
21 not limited to any analysis or reports by or from Dr. Gad regarding IVC filters.

22
23 **Request for Production No. 20:**

24 All communications with Dr. Scott Terratola regarding IVC filter efficacy, safety,
25 or performance, including but not limited to any analysis or reports by or from Dr.
26 Terratola regarding IVC filters.

Request for Production No. 21:

All internal information and reports by Bard regarding tracking, trending, or analysis with respect to any and all Bard IVC filters from 2003 through the present, including but not limited to:

- a. modes of failure,
- b. impact on patients,
- c. patient outcomes,
- d. the types or severity of events,
- e. failure, severity, or event codes,
- f. FDA codes, and/or
- g. the nature of events.

This request includes any and all reports generated on routine or irregular bases

Request for Production No. 22:

All documents relating to any and all annual internal audits of Bard's quality systems from 2003 through the present.

Request for Production No. 23:

All documents relating to any and all external audits of Bard's systems, processes, devices, or files that include files relating to IVC filters, its quality systems, or its complaint files.

Request for Production No. 24:

All Failure Mode Effect Analyses (FMEAs) for Bard IVC filters from 2003 through the present.

Request for Production No. 25:

All clinical severity checklists relating to IVC filters that have been in effect from any time from 2003 through the present.

Request for Production No. 26:

The complete employment files at Bard for:

- a. Chad Modra,
- b. Maureen Uebelocker,
- c. John Wheeler, and
- d. Judy Ludwig.

Request for Production No. 27:

All job descriptions for the positions held by Chad Modra, Maureen Uebelocker, John Wheeler, and Judy Ludwig in 2014 and 2015.

Request for Production No. 28:

All information packets, agendas and “output action items” for the meetings of the “management board” responsible for the management review process.

Request for Production No. 29:

Chad Modra’s file of notes and related materials for the meetings or actions of the “management board” responsible for the management review process.

Request for Production No. 30:

The notes or files of any other Bard employee relating to the meetings or actions of the “management board” responsible for the management review process.

Request for Production No. 31:

All documents that reflect or embody or have as any part of their subject matter the management board's guidelines or rules regarding injury frequency or severity for any Bard IVC filters.

Request for Production No. 32:

All documents relating to any and all Corrective and Preventative Actions (CAPA) relating to any Bard IVC filter.

Request for Production No. 33:

Any and all documents that demonstrate communications from the FDA regarding whether the failure of an IVC filter to deploy is a reportable event to the FDA, including but not limited to any correspondence from the FDA to Bard's medical director and any "meeting minutes" as testified to by Chad Modra.

Request for Production No. 34:

All documents that evince, relate, or refer to FDA guidance given to Bard regarding the classification of events for purposes of reporting adverse events to the FDA, including but not limited to all communications and correspondence with the FDA as well as internal Bard communications such as memoranda, emails, notes, and agendas.

Request for Production No. 35:

All internal communications (including all emails) of Bard employees and agents regarding the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, or Bard's responses thereto. This request specifically includes but is not limited to all communications regarding the

1 retrospective review of IVC filter complaint records and the reclassification of
2 reportability status for such records.

3
4 DATED this 4th day of January 2016.

5 **GALLAGHER & KENNEDY, P.A.**

6
7 By: 

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14 *Co-Lead/Liaison Counsel for Plaintiffs*

CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2016, a true and correct copy of the foregoing was sent via U.S. Mail and/or Electronic Mail to:

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*Counsel for Plaintiffs will be served in accordance with the Court's Case Management Order No. 1


Nancy Jo Koenes

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